

Attorney Docket No.: DEX-0115  
Inventors: Salceda et al.  
Serial No.: 09/717,883  
Filing Date: November 21, 2000  
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# I. Finality of Restriction Requirement

The Examiner has made final the Restriction Requirement as follows:

Group I, claims 1-2, drawn to a diagnostic marker comprising Ovr107, classified in class 536, subclass 24.31;

Group II, claims 3-7, drawn to a method of diagnosing, staging and monitoring cancer, classified in class 435, subclass 4;

Group III, claim 8, drawn to a method of identifying therapeutic agents for imaging and treating cancer, classified in class 435, subclass 7.1;

Group IV, claim 9, drawn to an antibody to Ovr107, classified in class 424, subclass 138.1;

Group V, claims 10-11, drawn to a method of imaging cancer, classified in class 424, subclass 9.3;

Group VI, claims 12-14, drawn to a method of treating cancer, classified in class 424, subclass 183.1;

Group VII, claim 15, drawn to a method of inducing an immune response, classified in class 424, subclass 184.1; and

Group VIII, claim 16, drawn to a vaccine comprising Ovr107, classified in class 424, subclass 184.1.

Accordingly, in an earnest effort to advance the prosecution

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Canceled Claims

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of this case, Applicants have canceled nonelected claims 1,2 and 8-16, without prejudice. However, in light of the finality of this Restriction Requirement, Applicants reserve the right to file a divisional patent application to this subject matter.

## **II. Objection to Abstract**

The objection to the Abstract was maintained because Applicants did not send a marked version with the last response. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants are providing a replacement Abstract and a marked version herewith which has been amended to enable the reader to ascertain quickly the character of the subject matter covered by this disclosure. No new matter has been added by this amendment. Withdrawal of the objection to the Abstract is respectfully requested in light of this amendment.

## **III. Rejection of Claims 3-7 under 35 U.S.C. § 112, first paragraph**

Claims 3-7 have been rejected under 35 U.S.C. § 112, first paragraph, as the Examiner suggests that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention

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commensurate in scope with these claims. The Examiner has acknowledged the specification to be enabling for diagnosis comprising an increase in Ovr107 nucleic acid levels and determining BCSG levels using nucleic acid based assays. However, the Examiner suggests that the specification does not reasonably provide enablement for diagnosis comprising determining an increase in Ovr107 levels other than nucleic acid levels.

Applicants respectfully traverse this rejection.

Applicants believe that skill in this art field is such that the skilled artisan could routinely adapt teachings in the specification relating to determining BCSG levels using nucleic acid based assays to a BCSG protein assay.

However, in an earnest effort to advance the prosecution of this case, Applicants have amended the claims to be drawn to determining levels of BCSGs which can be measured using nucleic acid based assays. Specifically, claims 3 through 7 have been amended to state that Ovr107 comprises SEQ ID NO:1 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO:1. Support for this amendment can be found in the specification at page 2, line 33, through page 3, line 8 and page 6, lines 13-21. Thus, now new matter has been added by these amendments.

*literal support*

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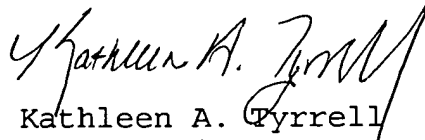
Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph is respectfully requested in light of these amendment.

#### IV. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

At page 28, please replace the paragraph at lines 2-4, with the following:

~~—The present invention provides new markers and methods for detecting, diagnosing, monitoring, staging, prognosticating, imaging and treating cancer.~~

A diagnostic marker for cancer referred to herein as Ovr107 is provided. Also provided are methods for using this marker to detect, diagnose, monitor, stage, prognosticate, image and treat cancer. Antibodies which specifically bind Ovr107 and methods of using these antibodies to image and treat cancer are also provided.

In the Claims:

Please cancel claims 1, 2, and 8-16, without prejudice.

Please amend the claims as follows:

3. (twice amended) A method for diagnosing the presence of cancer in a patient comprising:

(a) determining levels of Ovr107 in cells, tissues or bodily fluids in a patient, wherein Ovr107 comprises SEQ ID NO:1 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO:1; and

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(b) comparing the determined levels of Ovr107 with levels of Ovr107 in cells, tissues or bodily fluids from a normal human control, wherein an increase in determined levels of Ovr107 in said patient versus normal human control is associated with the presence of cancer.

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4. (amended) A method of diagnosing metastases of cancer in a patient comprising:

(a) identifying a patient having cancer that is not known to have metastasized;

(b) determining Ovr107 levels in a sample of cells, tissues, or bodily fluid from said patient, wherein Ovr107 comprises SEQ ID NO:1 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO:1; and

(c) comparing the determined Ovr107 levels with levels of Ovr107 in cells, tissue, or bodily fluid of a normal human control, wherein an increase in determined Ovr107 levels in the patient versus the normal human control is associated with a cancer which has metastasized.

5. (amended) A method of staging cancer in a patient having cancer comprising:

(a) identifying a patient having cancer;

(b) determining Ovr107 levels in a sample of cells, tissue, or bodily fluid from said patient, wherein Ovr107 comprises SEQ ID NO:1 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO:1; and

(c) comparing determined Ovr107 levels with levels of Ovr107 in cells, tissues, or bodily fluid of a normal human control, wherein an increase in determined Ovr107 levels in said patient versus the normal human control is associated with a cancer which is progressing and a decrease in the determined Ovr107 levels is associated with a cancer which is regressing or in remission.

6. (amended) A method of monitoring cancer in a patient for the onset of metastasis comprising:

(a) identifying a patient having cancer that is not known to

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have metastasized;

(b) periodically determining levels of Ovr107 in samples of cells, tissues, or bodily fluid from said patient, wherein Ovr107 comprises SEQ ID NO:1 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO:1; and

(c) comparing the periodically determined Ovr107 levels with levels of Ovr107 in cells, tissues, or bodily fluid of a normal human control, wherein an increase in any one of the periodically determined Ovr107 levels in the patient versus the normal human control is associated with a cancer which has metastasized.

7. (amended) A method of monitoring a change in stage of cancer in a patient comprising:

(a) identifying a patient having cancer;

(b) periodically determining levels of Ovr107 in cells, tissues, or bodily fluid from said patient, wherein Ovr107 comprises SEQ ID NO:1 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO:1; and

(c) comparing the periodically determined Ovr107 levels with levels of Ovr107 in cells, tissues, or bodily fluid of a normal human control, wherein an increase in any one of the periodically determined Ovr107 levels in the patient versus the normal human control is associated with a cancer which is progressing in stage and a decrease is associated with a cancer which is regressing in stage or in remission.